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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/594,927 | 12/21/2006 | Naoyuki Sato | 007123.00002 | 9493 |
| 22907 | 7590 | 05/14/2009 | EXAMINER | |
| BANNER & WITCOFF, LTD. 1100 13th STREET, N.W. SUITE 1200 WASHINGTON, DC 20005-4051 | | | | XU, XIAOYUN |
| ART UNIT | | PAPER NUMBER | | |
| 1797 | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/594,927 | SATO ET AL. | |
| | Examiner | Art Unit | |
| | ROBERT XU | 1797 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 28 April 2009.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-18,20 and 21 is/are pending in the application.
 4a) Of the above claim(s) 14,15 and 20 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-13,16-18 and 21 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>07/16/2008, 12/21/2006</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's election without traverse of group I comprising Claims 1-13, 16-18 and 21 in the reply filed on 04/28/2009 is acknowledged. Claims 1-20 are pending in the application. Claims 14, 15 and 20 are withdraw from consideration. Claims 1-13, 16-18 and 21 are considered on merits.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

3. **Claims 1-4, 8-10, 16-18 and 21** are rejected under 35 U.S.C. 102(a) as being anticipated by Ono et al. (Journal of Neurochemistry, 2003, IDS) (Ono).

In regard to Claims 1 and 8, Ono teaches a method of identifying a drug candidate capable of removing β -amyloid ($A\beta$) from fibril or aggregate formed *in vitro*, which comprises measuring, in the presence of a test compound (polyphenols), the concentrations of soluble β -amyloid ($A\beta$) in an equilibrium state in a solvent (see page 173, right col. 5th paragraph; right col. 1st paragraph).

In regard to Claim 2, Ono teaches that the drug candidate (polyphenols) is used for treatment of a disease caused by aggregation of amyloid β -peptide ($A\beta$) (see abstract).

In regard to Claim 3, Ono teaches that the disease is Alzheimer's disease (AD) (see abstract).

In regard to Claim 4, Ono teaches that the fibril was formed *in vitro* (see page 173, right col. Polymerization assay).

In regard to Claims 9 and 10, Ono teaches that the fibril or aggregate consists of $A\beta$ (1-40) and $A\beta$ (1-42) (see abstract).

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In regard to Claims 16 and 17, Ono discloses a dissolution promoter, myricetin, as an active ingredient, for removing β -amyloid ($A\beta$) from fibril or aggregate (see abstract). The compound is selected by the method described in Claim 1 (see page 173, right col. 5th paragraph; right col. 1st paragraph).

In regard to Claim 18, Ono teaches that the dissolution method comprises dissolving β -amyloid ($A\beta$) from fibril or aggregate, by the use of the compound obtained by the method described in claim 1 (see page 174, left col. 2nd paragraph; right col. 1st paragraph).

In regard to Claim 21, Ono teaches a method of identifying a drug candidate capable of removing β -amyloid ($A\beta$) from fibril or aggregate formed *in vitro*, which comprises measuring, in the presence of a test compound, the concentrations of soluble β -amyloid ($A\beta$) dissolved from fibril or aggregate in a solvent (see page 174, left col. 2nd paragraph; right col. 1st paragraph).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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6. **Claims 5-7 and 11-13** are rejected under 35 U.S.C. 103(a) as being unpatentable over Ono in view of Somerville et al. (Journal of General Virology, 1989) (Somerville).

In regard to Claims 5 and 11, Ono does not specifically teach that the equilibrium is achieved under ultrasonication. Somerville teaches that ultrasonication can reduce the formation of fibrils of brain protein (heterogeneous glycoprotein) called scrapie-associated fibrils (SAF) (see abstract). Since Ono studies how to reduce the formation of fibrils of peptide or protein with drug candidate, it would have been obvious to one of ordinary skill in the art to use ultrasonication as taught by Somerville to enhance the effect of the drug in Ono's method.

In regard to Claims 6 and 12, it is well known in the art that ultrasonication should be carried out substantially unaccompanied by heat generation, so that the protein will not be denatured. Ono teaches that ultrasonication is performed at 4°C (see page 173, right col. 2nd paragraph).

In regard to Claims 7 and 13, Ono in view of Somerville does not specifically teach the parameters of ultrasonication, because these parameters can be optimized by those skilled in the art through routine experimentation.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT XU whose telephone number is (571)270-5560. The examiner can normally be reached on Mon-Thur 7:30am-5:00pm, Fri 7:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on (571)272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

5/12/2009

/Yelena G. Gakh/
Primary Examiner, Art Unit 1797

RX